### 105TH CONGRESS 1ST SESSION

# H. R. 1055

To establish within the National Institutes of Health an agency to be known as the National Center for Integral Medicine, and for other purposes.

## IN THE HOUSE OF REPRESENTATIVES

March 13, 1997

Mr. DeFazio (for himself, Mr. Filner, Mr. Sanders, Ms. Norton, Mr. Moran of Virginia, Mr. Archer, Mr. Andrews, Mrs. Mink of Hawaii, Mr. Faleomavaega, Ms. Woolsey, Mr. Green, Mr. Rush, Mr. McDermott, Mr. Hinchey, Mr. Evans, and Mr. Foglietta) introduced the following bill; which was referred to the Committee on Commerce

# **A BILL**

To establish within the National Institutes of Health an agency to be known as the National Center for Integral Medicine, and for other purposes.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "National Center for
- 5 Integral Medicine Establishment Act".
- 6 SEC. 2. FINDINGS.
- 7 The Congress finds as follows:

- 1 (1) From 60 to 90 percent of chronic diseases
  2 may be largely prevented or treated by addressing
  3 lifestyle-related issues and using medical interven4 tions that stimulate and support natural healing
  5 processes.
  - (2) Behavioral, nutritional, preventive, and alternative medical approaches to disease prevention and treatment that emphasize these processes offer a possible solution to the successful management of many of our most devastating and costly chronic diseases.
  - (3) Interventions to address chronic diseases must involve the integration of these behavioral, nutritional, preventive, and alternative medical practices into conventional medical practices, including integration into health care delivery systems in the United States.
  - (4) Over 1/3 of the American public and 80 percent of the world's population make regular use of such practices.
  - (5) These practices are not usually available in the current conventional health care system nor evaluated in most research institutions, yet are vital for the provision of optimal health care.

1	(6) A center is needed for the support and inte-
2	gration of knowledge across all of the agencies of the
3	National Institutes of Health and across all medical
4	research activities pertaining to wellness and health
5	research, rather than further specialization of knowl-
6	edge based on the division of disease treatment cat-
7	egories.
8	SEC. 3. ESTABLISHMENT OF NATIONAL CENTER FOR INTE-
9	GRAL MEDICINE.
10	(a) In General.—Title IV of the Public Health
11	Service Act (42 U.S.C. 281 et seq.) is amended—
12	(1) in part A—
13	(A) in section 402, by striking subsection
14	$(\mathbf{f});$
15	(B) by striking section 404A; and
16	(C) by striking section 404E; and
17	(2) in part E, by amending subpart 4 to read
18	as follows:
19	"Subpart 4—National Center for Integral Medicine
20	"SEC. 485C. PURPOSE OF CENTER.
21	"(a) In General.—The general purposes of the Na-
22	tional Center for Integral Medicine (in this subpart re-
23	ferred to as the 'Center') are—
24	"(1) the conduct and support of basic and ap-
25	plied research (including clinical research), training,

- 1 the dissemination of health information, and other
- 2 programs, including prevention programs, with re-
- 3 spect to identifying and evaluating alternative medi-
- 4 cal treatment systems and disciplines, alternative
- 5 medical diagnostic systems and disciplines, and the
- 6 modalities of such treatment and diagnostic systems
- 7 and disciplines; and
- 8 "(2) carrying out the functions specified in sec-
- 9 tions 485D through 485F (relating to disease pre-
- vention, behavioral and social sciences research, and
- dietary supplements, respectively).
- 12 The Center shall be headed by a director, who shall be
- 13 appointed by the Secretary. The Director of the Center
- 14 shall report directly to the Director of NIH.
- 15 "(b) Advisory Council.—The Secretary shall es-
- 16 tablish an advisory council for the Center in accordance
- 17 with section 406, except that the members of the advisory
- 18 council who are not ex officio members shall include one
- 19 or more practitioners from each of the disciplines and sys-
- 20 tems with which the Center is concerned, including each
- 21 discipline and system in which accreditation, national cer-
- 22 tification, or a State license is available.
- 23 "(c) Complement to Conventional Medicine.—
- 24 In carrying out subsection (a), the Director of the Center
- 25 shall, as appropriate, promote the integration of alter-

- 1 native medical treatment and diagnostic systems and dis-
- 2 ciplines into the practice of conventional medicine as a
- 3 complement to such medicine, including the integration of
- 4 such systems and disciplines into health care delivery sys-
- 5 tems in the United States.
- 6 "(d) CERTAIN EVALUATION FACTORS.—In carrying
- 7 out subsection (a) with respect to an alternative medical
- 8 treatment system or discipline (including with respect to
- 9 particular modalities), the Director of the Center shall
- 10 consider the following factors:
- 11 "(1) The effectiveness of the system or dis-
- cipline as a treatment for the health condition in-
- volved, including effectiveness with respect to acute
- cases and effectiveness with respect to chronic cases
- 15 (as applicable).
- 16 "(2) The safety of the system or discipline, in-
- 17 cluding any adverse effects associated with use of
- the system or discipline.
- "(3) The costs of the system or discipline.
- 20 "(4) The extent to which the system or dis-
- 21 cipline promotes wellness and supports inherent
- healing processes.
- 23 "(5) Such other factors as the Director consid-
- ers appropriate.

- 1 "(6) A comparison of the system or discipline
- with conventional treatments for the health condi-
- 3 tion, which comparison shall be made in terms of the
- 4 factors specified in paragraphs (1) through (4) and
- 5 such factors as the Director may specify under para-
- 6 graph (5).
- 7 "(e) Evaluation of Various Disciplines and
- 8 Systems.—In carrying out subsection (a), the Director
- 9 of the Center shall identify and evaluate alternative medi-
- 10 cal treatment and diagnostic modalities in each of the dis-
- 11 ciplines and systems with which the Center is concerned,
- 12 including each discipline and system in which accredita-
- 13 tion, national certification, or a State license is available.
- 14 Disciplines or systems under the preceding sentence in-
- 15 clude acupuncture and Oriental medicine, homeopathic
- 16 medicine, physical manipulation therapies, chiropractic,
- 17 naturopathic medicine, midwifery, and such other systems
- 18 and disciplines as the Director of the Center determines
- 19 to be appropriate.
- 20 "(f) CERTAIN REQUIREMENTS.—The Director of the
- 21 Center shall conduct or support the following activities
- 22 with respect to alternative medical treatment and diag-
- 23 nostic systems and disciplines:
- 24 "(1) Research on outcomes.
- 25 "(2) Epidemiological activities.

1	"(3) Research training.
2	"(4) Health services research.
3	"(g) Data System; Information Clearing-
4	HOUSE.—
5	"(1) Data system.—The Director of the Cen-
6	ter shall establish a data system for the collection,
7	storage, analysis, and retrieval of data relating to al-
8	ternative medical treatment and diagnostic systems
9	and disciplines.
10	"(2) CLEARINGHOUSE.—The Director of the
11	Center shall establish an information clearinghouse
12	to facilitate and enhance, through the effective dis-
13	semination of information, knowledge and under-
14	standing of alternative medical treatment and diag-
15	nostic systems and disciplines by health profes-
16	sionals, patients, industry, and the public.
17	"(h) Research Centers.—
18	"(1) IN GENERAL.—The Director of the Center,
19	after consultation with the advisory council for the
20	Center, may provide support for the development
21	and operation of centers to conduct research and
22	other activities described in subsection (a)(1) with
23	respect to alternative medical treatment and diag-

nostic systems and disciplines.

1 "(2) Requirements.—Each center assisted 2 under paragraph (1) shall use the facilities of a sin-3 gle entity, or be formed from a consortium of cooperating entities, and shall meet such requirements 5 as may be established by the Director of the Center. 6 Each such center shall— "(A) be established as an independent en-7 8 tity; or 9 "(B) be established within or in affiliation 10 with an entity that conducts research or train-11 ing described in subsection (a)(1). "(3) Duration of Support.—Support of a 12 13 center under paragraph (1) may be for a period not 14 exceeding 5 years. Such period may be extended for 15 one or more additional periods not exceeding 5 years 16 if the operations of such center have been reviewed 17 by an appropriate technical and scientific peer re-18 view group established by the Director of the Center 19 and if such group has recommended to the Director 20 that such period should be extended. 21 "(i) BIENNIAL REPORT.—The Director of the Center 22 shall prepare biennial reports on the activities carried out 23 or to be carried out by the Center, and shall submit each such report to the Director of NIH for inclusion in the

biennial report under section 403.

- 1 "(j) Availability of Resources.—After consulta-
- 2 tion with the Director of the Center, the Director of NIH
- 3 shall ensure that resources of the National Institutes of
- 4 Health, including clinical facilities, are sufficiently avail-
- 5 able for activities of the Center.
- 6 "(k) AUTHORIZATION OF APPROPRIATIONS.—For the
- 7 purpose of carrying out this subpart, there are authorized
- 8 to be appropriated \$198,000,000 for fiscal year 1998, and
- 9 such sums as may be necessary for each of the fiscal years
- 10 1999 through 2002. Amounts appropriated under this
- 11 subsection for fiscal year 1998 are available for obligation
- 12 through September 30, 2000. Amounts appropriated
- 13 under this subsection for fiscal year 1999 are available
- 14 for obligation through September 30, 2000.
- 15 "SEC. 485D. OFFICE OF DISEASE PREVENTION.
- 16 "(a) IN GENERAL.—There is established within the
- 17 Center an office to be known as the Office of Disease Pre-
- 18 vention (in this section referred to as the 'Office'). The
- 19 Office shall be headed by a director, who shall be ap-
- 20 pointed by the Director of the Center. The Director of the
- 21 Center shall carry out the functions specified in this sec-
- 22 tion acting through the Director of the Office.
- 23 "(b) Duties.—
- 24 "(1) IN GENERAL.—The Director of the Office
- shall promote the disease prevention research pro-

grams of the national research institutes, and shall provide for the coordination of such programs among the national research institutes and between the national research institutes and other public and private entities, including elementary, secondary, and postsecondary schools.

- "(2) CERTAIN DUTIES.—The Director of the Office shall—
  - "(A) annually review the efficacy of existing policies and techniques used by the national research institutes to disseminate the results of disease prevention and behavioral research programs; and
  - "(B) recommend, coordinate, and oversee the modification or reconstruction of such policies and techniques to ensure maximum dissemination, using advanced technologies to the maximum extent practicable, of research results to such entities.
- "(c) BIENNIAL REPORT.—The Director of the Office shall prepare biennial reports on the activities carried out or to be carried out by the Office, and shall submit each such report to the Director of the Center for inclusion in the biennial report under section 485C(i). Each such report shall include—

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1	"(1) a summary of the Director's review of ex-
2	isting dissemination policies and techniques together
3	with a detailed statement concerning any modifica-
4	tion or restructuring, or recommendations for modi-
5	fication or restructuring, of such policies and tech-
6	niques; and
7	"(2) a detailed statement of the expenditures
8	made for the prevention and dissemination activities
9	reported on and the personnel used in connection
10	with such activities.
11	"SEC. 485E. OFFICE OF BEHAVIORAL AND SOCIAL
12	SCIENCES RESEARCH.
13	"(a) In General.—There is established within the
14	Center an office to be known as the Office of Behavioral
15	and Social Sciences Research (in this section referred to
16	as the 'Office'). The Office shall be headed by a director,
17	who shall be appointed by the Director of the Center. The
18	Director of the Center shall carry out the functions speci-
19	fied in this section acting through the Director of the Of-
20	fice.
21	"(b) Duties.—
	(//4) T
22	"(1) In general.—With respect to research on
<ul><li>22</li><li>23</li></ul>	"(1) IN GENERAL.—With respect to research on the relationship between human behavior and the de-

- 1 "(A) coordinate research conducted or sup-2 ported by the agencies of the National Insti-3 tutes of Health; and
  - "(B) identify projects of behavioral and social sciences research that should be conducted or supported by the national research institutes, and develop such projects in cooperation with such institutes.
- 9 "(2) Certain duties.—Research authorized 10 under paragraph (1) includes research on teen preg-11 nancy, infant mortality, violent behavior, suicide, 12 and homelessness. Such research does not include 13 neurobiological research, or research in which the 14 behavior of an organism is observed for the purpose 15 of determining activity at the cellular or molecular 16 level.
- "(c) BIENNIAL REPORT.—The Director of the Office shall prepare biennial reports on the activities carried out or to be carried out by the Office, and shall submit each such report to the Director of the Center for inclusion in the biennial report under section 485C(i).

#### 22 SEC. 485F. OFFICE OF DIETARY SUPPLEMENTS.

"(a) IN GENERAL.—There is established within the Center an office to be known as the Office of Dietary Supplements (in this section referred to as the 'Office'). The

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1	Office shall be headed by a director, who shall be ap-
2	pointed by the Director of the Center. The Director of the
3	Center shall carry out the functions specified in this sec-
4	tion acting through the Director of the Office.
5	"(b) Duties.—
6	"(1) In general.—The Director of the Office
7	shall—
8	"(A) expand the activities of the national
9	research institutes with respect to the potential
10	role of dietary supplements as a significant part
11	of the efforts of the United States to improve
12	health care; and
13	"(B) promote scientific study of the bene-
14	fits of dietary supplements in maintaining
15	health and preventing chronic disease and other
16	health-related conditions.
17	"(2) CERTAIN DUTIES.—The Director of the
18	Office shall—
19	"(A) conduct and coordinate scientific re-
20	search within the National Institutes of Health
21	relating to dietary supplements and the extent
22	to which the use of dietary supplements can
23	limit or reduce the risk of diseases such as
24	heart disease, cancer, birth defects,
25	osteoporosis, cataracts, or prostatism;

1	"(B) collect and compile the results of sci-
2	entific research relating to dietary supplements,
3	including scientific data from foreign sources or
4	other offices of the Center;
5	"(C) serve as the principal advisor to the
6	Secretary and to the Assistant Secretary for
7	Health and provide advice to the Director of
8	NIH, the Director of the Centers for Disease
9	Control and Prevention, and the Commissioner
10	of Food and Drugs on issues relating to dietary
11	supplements including—
12	"(i) dietary intake regulations;
13	"(ii) the safety of dietary supple-
14	ments;
15	"(iii) claims characterizing the rela-
16	tionship between dietary supplements and
17	the prevention of disease or other health-
18	related conditions;
19	"(iv) claims characterizing the rela-
20	tionship between dietary supplements and
21	the maintenance of health; and
22	"(v) scientific issues arising in connec-
23	tion with the labeling and composition of
24	dietary supplements;

1	"(D) compile a database of scientific re-
2	search on dietary supplements and individual
3	nutrients; and
4	"(E) coordinate funding relating to dietary
5	supplements for the National Institutes of
6	Health.
7	"(c) BIENNIAL REPORT.—The Director of the Office
8	shall prepare biennial reports on the activities carried out
9	or to be carried out by the Office, and shall submit each
10	such report to the Director of the Center for inclusion in
11	the biennial report under section 485C(i).
12	"(d) Definition.—For purposes of this section, the
13	term 'dietary supplement' has the meaning given such
14	term in section 201(ff) of the Federal Food, Drug, and
15	Cosmetic Act.".
16	(b) Technical And Conforming Amendments.—
17	Part A of title IV of the Public Health Service Act (42
18	U.S.C. 281 et seq.), as amended by subsection (a) of this
19	section, is amended—
20	(1) in section $401(b)(2)$ , by amending subpara-
21	graph (E) to read as follows:
22	"(E) The National Center for Integral Medi-
23	cine.";

- 1 (2) in section 402, by redesignating subsections
- 2 (g) through (k) as subsections (f) through (j), re-
- 3 spectively; and
- 4 (3) by redesignating sections 404B through
- 5 404D as sections 404A through 404C, respectively.

### 6 SEC. 4. SAVINGS PROVISIONS.

- 7 All officers and employees employed in the Office of
- 8 Alternative Medicine on the day before the date of the en-
- 9 actment of this Act (pursuant to section 404E of the Pub-
- 10 lie Health Service Act, as in effect on such day) are trans-
- 11 ferred to the National Center for Integral Medicine, in-
- 12 cluding the members and staff of the advisory council, and
- 13 there are transferred to such Center all funds of such Of-
- 14 fice available on such day and all other legal rights and
- 15 duties of such Office. With respect to the establishment
- 16 of a designated Center office pursuant to the amendments
- 17 made by section 3, such establishment shall be construed
- 18 to constitute a transfer of the designated Center office to
- 19 the National Center for Integral Medicine from the Office
- 20 of the Director of the National Institutes of Health (in
- 21 which the designated Center office was located pursuant
- 22 to the relevant former section of the Public Health Service
- 23 Act). A transfer referred to in the preceding provisions
- 24 of this section does not affect the status of any of the
- 25 officers or employees involved (except to the extent that

- the amendments made by section 3 affect the authority to make appointments to employment positions); does not 3 affect the availability of the funds for the purposes for which the funds were appropriated (except that in the case of such National Center such purposes shall apply with respect to the National Center to the same extent and in 6 the same manner as the purposes applied with respect to 8 the Office of Alternative Medicine); and does affect any other legal rights and duties, which continue in effect in 10 accordance with their terms. For purposes of this section: (1) The term "designated Center office" means each of 11 12 the Office of Disease Prevention (as established in section 13 485D of the Public Health Service Act, as added by the 14 amendments made by section 3 of this Act); the Office 15 of Behavioral and Social Sciences Research (as established in section 485E of such Act, as so added); and the Office 16 of Dietary Supplements (as established in section 485F) of such Act, as so added). (2) The term "relevant former 18 19 section of the Public Health Service Act", with respect to 20 a designated Center office, means, in the case of the Office 21 of Disease Prevention, section 402(f) of the Public Health 22 Service Act as in effect on the day before the date of the
- 25 Act as in effect on such day; and in the case of the Office

enactment of this Act; in the case of the Office of Behav-

ioral and Social Sciences Research, section 404A of such

- 1 of Dietary Supplements, section 485C of such Act as in
- 2 effect on such day.

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